TECHNICAL SPECIFICATION.

Product Name

First Response® Malaria Ag. *P.f.* / *P.v.* Card Test

Manufacturer: Premier Medical Corporation Private Limited

**A1-302, GIDC, Sarigam-396155. Dist. Valsad,
Gujarat, INDIA.**

An ISO 13485 & EN ISO 13485 Certified Company

Product Details			
1	Product Name	:	First Response® Malaria Ag. *P.f. / P.v.* Card Test
2	Product Family	:	In Vitro Diagnostic Tests
3	Product Code	:	PI19FRC

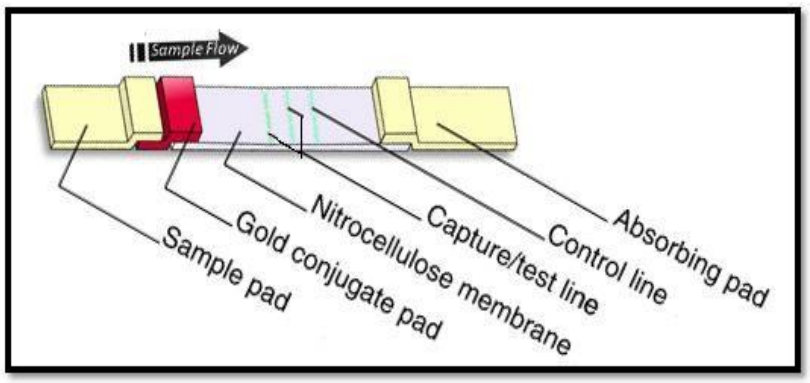
Intended Use:

First Response® Malaria Ag. *P.f. / P.v.* Card Test is intended to be performed by trained users and as qualitative screening *in vitro* diagnostic test for detection of *P. falciparum* and *P. vivax.* The test is intended for use with human whole blood specimens (capillary or venous blood). Venous blood with the following anti-coagulants such as heparin, EDTA or citrate do not affect the test results. The test is not automated and does not require any additional instrument.

Assay Principle

First Response® Malaria Ag. *P.f. / P.v.* Card Test is based on principle of immunochromatography in which nitrocellulose membrane is pre-coated with two monoclonal antibodies as two separate lines. One monoclonal antibody (test line P.v.) is *P. vivax* specific to Lactate Dehydrogenase (pLDH) and the other line (test line P.f.) consists of a monoclonal antibody specific to Histidine-Rich Protein 2 (HRP2) of the *Plasmodium falciparum*. When the test sample along with assay buffer flows through the nitrocellulose membrane, monoclonal antibodies conjugated with colloidal gold, which are *P.vivax* specific to pLDH and *P. falciparum* specific to HRP2 binds to *Plasmodium* antigens released from the lysed blood sample. These antigen-conjugated antibody complex moves through the nitrocellulose membrane and binds to corresponding immobilised antibody at test lines, which leads to the formation of colour line / lines indicating reactive results. The control line will appear irrespective of reactive or non reactive sample. So, the First Response® Malaria Ag. *P.f. / P.v.* Card Test is "of additional value" in the differential diagnosis of *Plasmodium falciparum* and *P. vivax.*

General Presentation of test strip of First Response®Malaria Ag. *P.f. / P.v.* Card Test



Storage & Stability

First Response® Malaria Ag. *P.f. / P.v.* Card Test should be stored at 1 - 40°C. Do not freeze the kit or components. Assay buffer (opened & unopened) & the unopened Test Device are stable until the expiry date printed on the label, when stored at 1 - 40°C. The test device is sensitive to humidity and heat. Perform the test immediately after removing the Test Device from the foil pouch. The shelf life of the kit is as indicated on the outer package. Do not use Test Device and Assay Buffer beyond the date of expiry.

Shelf Life:

First Response® Malaria Ag. *P.f. / P.v.* Card Test has shelf life of 24 months.

Performance Characteristics:

Based on the demonstrated P. *falciparum* panel detection score (94.0% at 200 parasites/µl), P. *vivax* panel detection score (97.1% at 200 parasites/µl), false-positive rates (1.4% for clean negatives, 0.8% for P. *falciparum* at 200 parasites/µl, 1.4% for P. *vivax* at 200 parasites/µl, 0.5% for P. *falciparum* at 2000 to 5000 parasites/µl, 1.4% for P. *vivax* at 2000 to 5000 parasites/µl) and invalid rate (0.1%).

Operational Characteristics:

Temperature range:

- First Response® Malaria Ag. *P.f. / P.v.* Card Test is stable at temperature range of 1-40°C.
- Operating Temperature range is room temperature.
- Test result interpretation time 20 minutes.

Certification:

- First Response® Malaria Ag. *P.f. / P.v.* Card Test is WHO pre-qualified product.
- First Response® Malaria Ag. *P.f. / P.v.* Card Test is manufactured by Premier Medical Corporation Pvt Ltd is ISO 13485 & EN ISO 13485 certified company.

Kit components:

Each kit of First Response® Malaria Ag. *P.f. / P.v.* Card Test contains:

- Test devices packed in aluminum pouch with desiccant,
- Specimen transfer device,
- Sterile lancets,
- Alcohol swabs,
- Instruction for use in English language,
- Assay buffer bottle.